

REMARKS

Reconsideration is requested.

The Amendment filed December 16, 2008 has been entered and the Amendment has overcome the Section 103 rejection of claims 12-14, 16-22, 27 and 29-32 over Petyaev (WO 03/017992) and Shiff (U.S. Patent No. 6,201,028).¹

The claims have been further amended to advance prosecution, without prejudice. Claim 22 has been canceled, without prejudice. Claims 35-38 have been added, based on claims 13, 29, 33, 34, but dependent from claim 21. No new matter has been added.

Claims 12, 13, 21, 22, 29 and 32-34 are pending.

To the extent not obviated or moot in view of the above, the Section 103 rejection of claims 12-14, 16-22 and 29-32 over Klein (U.S. Patent No. 6,174,865) and Shiff (U.S. Patent No. 6,201,028) is traversed. Reconsideration and withdrawal of the rejection are requested in view of the above and the following further comments.

The Examiner has alleged that it would have been *prima facie* obvious for a person having ordinary skill in the art at the time the invention was made to have combined azithromycin with aspirin in a simultaneous administration for the treatment of hyperlipidemia.

The presently claimed invention relates to the reduction in the apolipoprotein-B levels in the vascular system of an individual with hyperlipidemia without a concomitant reduction in LDL-cholesterol levels. Independent claims 12, 21 and 32 specify that the

¹ See Advisory Action dated January 9, 2009.

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active ingredients aspirin and azithromycin are administered simultaneously and in amounts which are sufficient to

Klein does not disclose or suggest any effect of azithromycin on LDL levels or ApoB and indeed teaches that, while erythromycin compounds, such as azithromycin, reduce triglyceride levels, they have little or no effect on LDL.

Shiff discloses a statistically insignificant effect of aspirin on plasma cholesterol but does not disclose any effect of aspirin on levels of LDL or ApoB.

The combination of Klein and Shiff is devoid of any suggestion that apolipoprotein-B levels in the vascular system might be reduced without causing a concomitant reduction LDL-cholesterol levels. This technical effect was unexpected from the cited art and one of ordinary skill in the art would not have arrived at the claimed methods for reducing apolipoprotein-B levels from the combined teachings of Klein and Shiff .

Withdrawal of the Section 103 rejection of claims 12-14, 16-22 and 29-32 over Klein and Shiff et al is requested.

The claims are submitted to be in condition for allowance and a Notice of Allowance are requested. The Examiner is requested to contact the undersigned, preferably by telephone, in the event anything further is required.

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Respectfully submitted,

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